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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,604	06/26/2002	Alex Bollen	B45168	2758

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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/868,604

Applicant(s)

BOLLEN ET AL.

Examiner

Mark Navarro

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-78 is/are pending in the application.
- 4a) Of the above claim(s) 35-48, 55, 57-60, 66-71, 77 and 78 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 32, 63 and 74 is/are allowed.
- 6) ☒ Claim(s) 30, 33, 34, 49-54, 56, 61, 62, 64, 65, 72, 75 and 76 is/are rejected.
- 7) ☒ Claim(s) 31, 62 and 73 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment filed November 12, 2004 has been received and entered. Accordingly, claims 30-78 are pending in the instant application, of which claims 35-46, 48-60, 66-71, and 77-78 have been withdrawn from further consideration as being drawn to a non-elected invention. Additionally, Applicant's have elected SEQ ID NO: 42 for prosecution.

Election/Restrictions

Note: Although claim 47 was included in the elected group I proteins (i.e., claims 30-34, 47, 61-65 and 72-76), claim 47 (process of culturing a host cell to produce a polypeptide) clearly belongs with the group of claims classified as DNA. This is deemed to have been a typographical error on the part of the previous Examiner. Accordingly, the instant Examiner will withdraw claim 47 from consideration and properly place it in the non-elected group II. The Examiner apologizes for this error. Likewise, claims 49-53 and 56 are clearly drawn to proteins, as such these claims have been rejoined with the instantly elected Group I. Note claim 56 will be examined to the extent it reads on proteins (dependency on claims 49-54), not its dependency on claim 55 to nucleotides.

Accordingly, claims 30-78 are pending in the instant application, of which claims 35-48, 55, 57-60, 66-71, and 77-78 have been withdrawn from further consideration as being drawn to a non-elected invention. Additionally, Applicant's election of SEQ ID NO: 42 for prosecution remains unaffected.

Priority

Applicants argument that SEQ ID NO: 42 was disclosed in UK application 9828217.1 are persuasive. Accordingly, Applicants date of foreign priority to June 20, 2001 for the instantly filed claims is accepted.

All grounds of rejection in the previous Office Action mailed May 19, 2004 are withdrawn in view of Applicants arguments.

The following new grounds of rejection are applied:

Claim Rejections - 35 USC § 112

1. Claims 30, 33-34, 49, 52-53, 56, 61, 64-65, 72, and 75-76 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 30, 33-34, 49, 52-53, 56, 61, 64-65, 72, and 75-76 recite polypeptides which have 75% identity to SEQ ID NO: 42, or "comprising" a fragment of 10 consecutive amino acids of SEQ ID NO: 42.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural

variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "SEQ ID NO: 42" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed."

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Furthermore, in *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention."

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

2. Claims 49-54, and 56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic compositions, does not reasonably provide enablement for vaccine compositions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir 1999).

First, as set forth by Plotkin et al (VACCINES W.B. Saunders Company, 1988, page 571) "The key to the problem (of vaccine development) is the identification of that protein

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component of a virus or microbial pathogen that itself can elicit the production of protective antibodies... and thus protect the host against attack by the pathogen.” This teaching directly addresses factors 1, 4, 5, 6, 7 and 8.

Second, Applicants specification provides no working examples demonstrating treatment or prevention with the polypeptides of the instant inventions. This directly affects Factors 1, 2, 3, 4 and 8.

A vaccine “must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough.” In re Wright, 999 F.2d 1557,1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

Given the lack of guidance, lack of working examples, and the unpredictable nature of the invention, one of skill in the art would be forced into excessive experimentation in order to practice the instantly claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 33-34 and 75-76 are rejected under 35 U.S.C. 102(b) as being anticipated by Meinhardt et al.

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The claims are directed to an isolated polypeptide comprising a fragment having 10 consecutive amino acids of the polypeptide as claimed in claims 30-32.

Meinhardt et al (Molecular Microbiology Vol 9, No. 1, pp 17-29, 1993) disclose of isolated polypeptides which comprise 10 or more consecutive amino acids from the recited polypeptides. (See page 20, sequence comprising AQFERALAQA).

Claims 31, 62, 73 are objected to for depending upon a rejected base claim, however claims 31, 62 and 73 are free of the prior art of record.

Claims 32, 63, 74 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
February 1, 2005